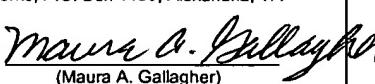


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PATENT & TRADEMARK OFFICE

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Dated: 11-18-04

Signature:   
(Maura A. Gallagher)

Docket No.: MIY-P01-024  
(PATENT)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:  
Chu et al.

Application No.: 10/642395

Confirmation No.: 9490

Filed: August 14, 2003

Art Unit: 3731

For: SYSTEMS, METHODS AND DEVICES  
RELATING TO DELIVERY OF MEDICAL  
IMPLANTS

Examiner: Not Yet Assigned

### INFORMATION DISCLOSURE STATEMENT

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)).

A copy of the non US references listed on the PTO/SB/08 is attached. A summary/abstract translation of the non-English language references is enclosed where applicable.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this

Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

Applicants call the Examiner's attention to office actions which may have issued in the following co-pending, co-owned patent applications of which subject matters are related to that of the instant application:

<b>U.S. Patent Application Serial Number</b>	<b>Filing Date</b>
10/093,371	March 7, 2002
10/093,398	March 7, 2002
10/093,424	March 7, 2002
10/093,450	March 7, 2002
10/093,498	March 7, 2002
10/094,354	March 7, 2002
10/642,397	August 14, 2003
10/642,365	August 14, 2003
10/641,487	August 14, 2003

Applicants have become aware of the following documents: U.S. Patent No. 6,312,448; U.S. Patent No. 5,904,692; WO 00/74594; EP 1159920; and U.S. Patent No. 5,899,909, cited in

an International Search Report issued August 20, 2004, during the prosecution of international application no. PCT/US03/25568, which corresponds to the above referenced application, and in accordance with 37 CFR 1.97(c) and (e)(1) or (b)(3), hereby submits these documents for the Examiner's consideration. These documents are cited on the enclosed PTO Form SB/08, and a copy of the International Search Report and each document cited thereon are enclosed as well.

This statement is not to be interpreted as a representation that the cited documents are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any document herein be construed *per se* as a representation that such document is prior art. Moreover, Applicant(s) understand(s) the Examiner will make an independent evaluation of the cited documents.

The undersigned hereby certifies that each item contained in this Information Disclosure Statement was cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 18-1945, under Order No. MIY-P01-024.

Dated: November 18, 2004

Respectfully submitted,

By   
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JFW

PTO/SB/21 (04-04)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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## TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

		Application Number	10/642395
		Filing Date	August 14, 2003
		First Named Inventor	Michael S. H. Chu
		Art Unit	N/A
		Examiner Name	Not Yet Assigned
Total Number of Pages in This Submission		Attorney Docket Number	MIY-P01-024

### ENCLOSURES (Check all that apply)

<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance communication to Technology Center (TC)
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment/Reply	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Terminal Disclaimer	<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Request for Refund	1. IDS FORM SB/08 (7 pages) 2. References A1-A188, B1-B28, and C1-C41 3. Copy of International Search Report (11 pages) 4. Return Receipt Postcard
<input checked="" type="checkbox"/> Information Disclosure Statement (3 pages)	<input type="checkbox"/> CD, Number of CD(s) _____	
<input type="checkbox"/> Certified Copy of Priority Document(s)		
<input type="checkbox"/> Response to Missing Parts/ Incomplete Application		
<input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53		
Remarks		

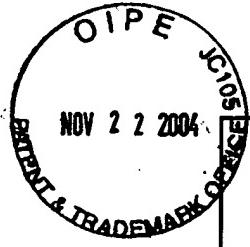
### SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	ROPES & GRAY LLP Weishi Li - 53,217
Signature	
Date	November 18, 2004

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Dated: 11-18-04

Signature: Maura A. Gallagher (Maura A. Gallagher)



PTO/SB/08a/b (08-03)  
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE  
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Substitute for form 1449A/B/PTO				<b>Complete If Known</b>	
				Application Number	10/642395
				Filing Date	August 14, 2003
				First Named Inventor	Michael S. H. Chu
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	1	of	7	Attorney Docket Number	MIY-P01-024

<b>U.S. PATENT DOCUMENTS</b>					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
A1	D466213 S		11/26/02	Snitkin et al.	
A2	2,738,790		3/20/56	Todt Sr., et al.	
A3	2,751,903		6/26/56	Ivory et al.	
A4	2,917,878		12/22/59	Edwin et al.	
A5	3,472,232		10/14/69	Earl et al.	
A6	3,565,073		2/23/71	Giesy	
A7	3,699,969		10/24/72	Allen	
A8	3,704,712		11/28/72	Giesy et al.	
A9	3,710,795		1/16/73	Higuchi et al.	
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A11	3,875,937		4/8/75	Schmitt et al.	
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A17	4,367,816		1/11/83	Wilkes	
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A19	4,445,898		5/1/84	Jensen	
A20	4,535,768		8/20/85	Hourahane et al.	
A21	4,592,339		6/3/86	Kuzmak et al.	
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A29	4,798,193		1/17/89	Giesy et al.	
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A34	4,896,668		1/30/90	Popoff et al.	
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A39	4,983,168		1/8/91	Moorehead	
A40	4,988,339		1/29/91	Vadher	
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A42	5,013,292		5/7/91	Lemay	
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A44	5,078,730		1/7/92	Li	
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Examiner Signature	Date Considered
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Substitute for form 1449A/B/PTO				<b>Complete If Known</b>	
				Application Number	10/642395
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				First Named Inventor	Michael S. H. Chu
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	2	of	7	Attorney Docket Number	MIY-P01-024

A47	5,087,263	2/11/92	Li	
A48	5,089,013	2/18/92	Bezwada et al.	
A49	5,112,344	5/12/92	Petros	
A50	5,133,723	7/28/92	Li et al.	
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Examiner Signature	Date Considered
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Substitute for form 1449A/B/PTO				<b>Complete if Known</b>	
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				First Named Inventor	Michael S. H. Chu
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	3	of	7	Attorney Docket Number	MIY-P01-024

A96	5,766,221	6/16/98	Benderev et al.	
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Examiner Signature	Date Considered
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Substitute for form 1449A/B/PTO				<b><i>Complete If Known</i></b>	
				Application Number	10/642395
				Filing Date	August 14, 2003
				First Named Inventor	Michael S. H. Chu
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	4	of	7	Attorney Docket Number	MIY-P01-024

A145	6,638,211	10/28/03	Suslian et al.	
A146	6,641,525	11/4/03	Rocheleau et al.	
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A164	2002/0099259	7/25/02	Anderson et al.	
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A187	2003/0191480	10/9/03	Ulmsten	
A188	2004/0015048	1/22/04	Neisz et al.	

Examiner Signature	Date Considered
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				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	5	of	7	Attorney Docket Number	MIY-P01-024

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code <sup>2</sup> -Number <sup>3</sup> -Kind Code <sup>4</sup> (if known)			
	B1	DE 2,305,815 A1	8/8/74		
	B2	DE 2,532,242 A1	2/10/77		
	B3	DE 43 34 419 A1	4/13/95	Univ. Ludwigs Albert	
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	B10	EP 0 140 557 A3	5/8/85	Blackwood	
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	B24	WO 96/01597	1/25/96	Dacomed Corporation	
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	B27	WO 97/13465	4/17/97	Medscand Medical	
	B28	WO 98/12971	4/2/98	Medworks Corporation	

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NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city			T <sup>2</sup>
Examiner Signature		Date Considered			

Substitute for form 1449A/B/PTO				<b>Complete If Known</b>	
				Application Number	10/642395
				Filing Date	August 14, 2003
				First Named Inventor	Michael S. H. Chu
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
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		and/or country where published.
C1	Bayer et al., "A New Approach To Primary Strengthening Of Colostomy With Marlex Mesh To Prevent Paracolostomy Hernia," <i>Surgery, Gynecology &amp; Obstetrics</i> , 163:579-580, (1986).	
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C3	Benderev, "Anchor Fixation And Other Modifications Of Endoscopic Bladder Neck Suspension," <i>Urology</i> , 40:409-418 (1992).	
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C5	Delorme, "La Bandelette Trans-Obturatrice: Un Procede Mini-Invasif Pour Traiter l'incontinence Urinaire D'effort De La Femme," <i>Progres En Urologie</i> , 11:1306-1313, (2001) (English Translation Provided).	
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C12	Mattox et al., "Modification Of The Miya Hook In Vaginal Colpopexy," <i>J. Reproductive Medicine</i> , 40:681-683 (Oct. 1995).	
C13	Mitchell, "Hook Needle And Retractor For Posterior Urethroplasty," <i>J. Urology</i> , 42:599-600 (1970).	
C14	Nativ et al., "Bladder Neck Suspension Using Bone Anchors for the Treatment of Female Stress Incontinence," <i>Asao Journal</i> , 204-208 (1997).	
C15	Norris et al., "Use Of Synthetic Material in Sling Surgery: A Minimally Invasive Approach," <i>J. Endourology</i> , 10:3, 227-230 (1996).	
C16	Pereyra, "A Simplified Procedure for the Correction of Stress Incontinence in Women," <i>West J. Surg. Obstetrics and Gynecology</i> , 223-226 (1959).	
C17	Petros et al., "Urethral Pressure Increase on Effort Originates From Within The Urethra, and Continence From Musculovaginal Closure," <i>Neurology and Urodynamics</i> , 14:4, 337-350 (1995).	
C18	Petros, "Ambulatory Surgery For Urinary Incontinence And Vaginal Prolapse," <i>Medical Journal Of Australia</i> , 161:171-172 (1994).	
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C20	Petros, et al., "An Integral Theory and its Method For The Diagnosis and Management of Female Urinary Incontinence," <i>Scandinavian J. Urology And Nephrology</i> , Supplement 153, 1-93 (1993).	
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C23	Raz et al., "Fascial Sling to Correct Male Neurogenic Sphincter Incompetence: The McGuire/Raz Approach," J. Urology, 139:528-531 (1988).	
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C31	Staskin et al., "The Gore-Tex Sling Procedure for Female Sphincteric Incontinence: Indications, Technique, and Results," World J. Urology, 15:5, 295-299, (1997).	
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C34	Ulmsten et al., "A Multicenter Study of Tension-Free Vaginal Tape (TVT) for Surgical Treatment of Stress Urinary Incontinence," Int Urogynecol J., 9:4, 210-213, (1998).	
C35	Ulmsten et al., "A Three-Year Follow Up of Tension Free Vaginal Tape for Surgical Treatment of Female Stress Urinary Incontinence," British J. Of Obstetrics And Gyn., 106, 345-350, (1999).	
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C38	Ulmsten et al., "Connective Tissue Factors in the Aetiology of Female Pelvic Disorders," Ann. Med., 22:6, 3 (1990).	
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